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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

KING PHARMACEUTICALS, INC., KING PHARMACEUTICALS RESEARCH AND DEVELOPMENT, INC. AND PHARMACEUTICAL IP HOLDING, INC., Plaintiffs, v. SANDOZ INC., Defendant.	Civil Action No. 3:08-cv-05974-GEB-DEA **DOCUMENT ELECTRONICALLY FILED** **RETURN DATE: DEC. 20, 2010**

SANDOZ'S OPPOSITION TO PLAINTIFFS' RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW, OR IN THE ALTERNATIVE, A NEW TRIAL, ON VALIDITY AND INFRINGEMENT

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I. INTRODUCTION

Sandoz Inc. ("Sandoz") submits this memorandum in opposition to the *Renewed Motion for Judgment as a Matter of Law, or in the Alternative, a New Trial, on Validity and Infringement* [D.E. 357], filed by plaintiffs King Pharmaceuticals, Inc., King Pharmaceuticals Research and Development, Inc. (collectively "King") and Pharmaceutical IP Holding, Inc. ("Pharma IP", and with King, collectively "Plaintiffs").

A. Background

Plaintiffs brought this case against Sandoz for infringement of U.S. Patent No. 7,122,566 ("the '566 Patent"). A jury trial was held from September 7, 2010 through September 16, 2010. At the conclusion of the trial, the jury found that Sandoz did not infringe any asserted claim of the '566 Patent and that all asserted claims were invalid.

Following the Court's denial of Plaintiffs' motion for a preliminary injunction [D.E. 120], Plaintiffs, in their *First Amended Complaint for Patent Infringement*, filed on June 1, 2010 [D.E. 131, p. 6], requested a trial by jury, which the Court permitted over Sandoz's objection [D.E. 129, May 26, 2010 hearing tr., pp. 4-5]. The jury having found against Plaintiffs on every issue, Plaintiffs now ask the Court to closely scrutinize the verdict because patent infringement is beyond the ordinary

knowledge of jurors. Plaintiffs' JMOL brief, p. 23.[1] Because there was more than sufficient evidence to sustain the jury's verdict, Plaintiffs' hypocritical motion to overturn the jury's verdict should be denied.

II. ARGUMENT

The right to a trial by jury is a bedrock principle of American jurisprudence, enshrined in the Bill of Rights. Setting aside a jury verdict is not to be done lightly, and the standard for such extraordinary relief is high.

A. Judgment as a Matter of Law

The Third Circuit[2] has succinctly explained the movant's difficult burden on a motion for judgment as a matter of law ("JMOL"):

> a judgment notwithstanding the verdict [now JMOL] may be granted under Fed. R. Civ. P. 50(b) "only if, as a matter of law, the record is critically deficient of that minimum quantity of evidence from which a jury might reasonably afford relief."

Trabal v. Wells Fargo Armored Service Corp., 269 F.3d 243, 249 (3d Cir. 2001), quoting *Powell v. J.T. Posey Co.*, 766 F.2d 131, 133-134 (3d Cir. 1985); *Wagner v.*

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[1] References to "Plaintiffs' JMOL brief" are to Plaintiffs' Memorandum of Law in Support of Their Renewed Motion for Judgment as a Matter of Law, or in the Alternative, a New Trial, on Validity and Infringement [D.E. 357-1].

[2] Although this is a patent case, and appeal is to the Court of Appeals for the Federal Circuit, the issue of whether a party has met the standards for JMOL under Fed. R. Civ. P. 50, or for a new trial under Fed. R. Civ. P. 59, is governed by the law of the regional circuit. *Wordtech Systems, Inc. v. Integrated Networks Solutions, Inc.*, 609 F.3d 1308, 1312 (Fed. Cir. 2010) ("We review denial of post-trial motions for JMOL and new trial under regional circuit law," citing *Revolution*

Fair Acres Geriatric Center, 49 F.3d 1002, 1012 (3d Cir. 1995) (in resolving a motion for judgment as a matter of law, the Court must give the "verdict winner, the benefit of all logical inferences that could be drawn from the evidence presented, resolve all conflicts in the evidence in her favor and, in general, view the record in the light most favorable to her"); *Williamson v. Consolidated Rail Corp.*, 926 F.2d 1344, 1348 (3d Cir. 1991) (same); *Church & Dwight Co. v. Abbott Labs.*, Civ. No. 05-2142, 2008 U.S. Dist. LEXIS 49591, *4 (D.N.J. June 24, 2008) ("A motion for judgment as a matter of law under Federal Rule of Civil Procedure 50(b) 'should be granted only if, viewing the evidence in the light most favorable to the non movant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury reasonably could find' for the non-movant," quoting *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1166 (3d Cir. 1993)); *Matsushita Elec. Indus. Co. v. Samsung Elecs. Co.*, Civ. No. 02-336, 2006 U.S. Dist. LEXIS 80145, *4-*5 (D.N.J. Nov. 2, 2006) (same).

"In considering a motion for judgment n.o.v., a court is not free to weigh the evidence, pass on the credibility of witnesses, or substitute its judgment of the facts for that of the jury." *Aloe Coal Co. v. Clark Equipment Co.*, 816 F.2d 110, 113 (3d Cir. 1987), citing *Blair v. Manhattan Life Insurance Co.*, 692 F.2d 296, 300 (3d Cir. 1982). Those decisions are the inviolable purview of the jury.

Eyewear, Inc. v. Aspex Eyewear, Inc., 563 F.3d 1358, 1370 (Fed. Cir. 2009)).

The Supreme Court has likewise recognized the sanctity of the jury's fact findings:

> It is the jury, not the court, which is the fact-finding body. It weighs the contradictory evidence and inferences, judges the credibility of witnesses, receives expert instructions, and draws the ultimate conclusion as to the facts. . . . Courts are not free to reweigh the evidence and set aside the jury verdict merely because the jury could have drawn different inferences or conclusions or because judges feel that other results are more reasonable.

Tennant v. Peoria & Pakin Union Ry. Co., 321 U.S. 29, 35 (1944) (citations omitted). If the evidence adduced at trial would allow a rational jury to draw a particular inference, "[n]o court is then justified in substituting its conclusions for those of the . . . jurors." *Id.* at 33.

Thus, JMOL should be granted only where there is an overwhelmingly strong case that the jury erred. Yet, here, the evidence overwhelmingly supports the jury's verdict, and Plaintiffs' motion for JMOL should be denied.

1. There was Sufficient Evidence to Support the Jury's Verdict of Non-Infringement.

To prove infringement, Plaintiffs had the burden to prove by a "preponderance of the evidence … that Sandoz's actions meet all the requirements of an asserted claim." Ex. 1,[3] Sept. 16, 2010 trial tr., 17:4-6 (jury charge). The Court further instructed the jury "[i]f you find a claim on which other claims depend is not

[3] All exhibits referenced herein are attached to the accompanying Declaration of Eric I. Abraham.

infringed, there can't be infringement of any of the dependent claims that refer to that independent claim." *Id.*, 17:16-19 (jury charge).

Claims 1, 5, and 6 are the only independent claims of the '566 Patent. Under the Court's charge, if Plaintiffs failed to meet their burden of proving infringement of those claims, the jury could not find infringement of the dependent claims.

Because Plaintiffs refer to claim 1 of the '566 patent as representative of the independent claims (Plaintiffs' JMOL brief, pp. 2-3), Sandoz does likewise.

a) Claim 1

Claim 1 of the '566 Patent reads:

> 1. A method of using metaxalone for treating a patient's condition, comprising:
>
> providing a patient with metaxalone; and
>
> informing the patient or a medical care worker that metaxalone affects activity of a cytochrome p450 isozyme, and that administration of metaxalone with a substance that affects activity of a cytochrome p450 isozyme can affect plasma concentration, safety, efficacy or any combination thereof of metaxalone, the substance, or both.

Ex. 2, PTX 1, col. 64, lines 47-56.

Claim 1 has two steps,[4] (1) "providing" metaxalone to a patient, and (2) "informing" the patient or a medical care worker (a) that metaxalone affects activity of a cytochrome p450 isozyme, and (b) that administration of metaxalone with a

[4] The parties agreed that the preambles of the claims are not claim limitations. Ex.

substance that affects activity of a cytochrome p450 isozyme can affect plasma concentration, safety, efficacy or any combination thereof of metaxalone, the substance, or both.

At trial, Sandoz did not dispute that it performed the first step, *i.e.*, providing metaxalone to patients. Sandoz also did not dispute that its package insert informs a patient or a medical care worker that metaxalone affects activity of a cytochrome p450 isozyme ((a) above). However, Sandoz did dispute -- and the evidence at trial showed -- that Sandoz does not inform "a patient or medical care worker … that administration of metaxalone with a substance that affects activity of a cytochrome p450 isozyme can affect plasma concentration, safety, efficacy or any combination thereof of metaxalone, the substance, or both." ((b) above).

The Court charged the jury that "[i]nforming" means "[r]eferring to or providing, published material, or presenting information orally, or demonstrating the intended information to a user for the purpose of comprehension." Ex. 4, *Post-Trial Jury Instructions and Jury Verdict Form*, p. 12.

At trial, Plaintiffs relied upon the following sections of Sandoz's package insert to show that Sandoz meets the "informing" step of the claims:

DISTRIBUTION, METABOLISM AND EXCRETION

…

3, JTX 1, p. 13.

> Metaxalone does not significantly inhibit major CYP enzymes such as CYP1A2, CYP2A6, CYP2B6, CYP2C8, CYP2C9, CYP2C19, CYP2D6, CYP2E1, and CYP3A4. Metaxalone does not significantly induce major CYP enzymes such as CYP1A2, CYP2B6, and CYP3A4 In vitro.
>
> ...
>
> **WARNINGS**
>
> Metaxalone tablets may enhance the effects of alcohol and other CNS depressants.
>
> ...
>
> **INFORMATION FOR PATIENTS**
>
> Metaxalone tablets may impair mental and/or physical abilities required for performance of hazardous tasks, such as operating machinery or driving a motor vehicle, especially when used with alcohol or other CNS depressants.
>
> ...
>
> **Drug Interactions**
>
> The sedative effects of metaxalone and other CNS depressants (e.g., alcohol, benzodiazepines, opiods, tricyclic antidepressants) may be additive. Therefore, caution should be exercised with patients who take more than one of these CNS depressants simultaneously.
>
> ...
>
> **OVERDOSAGE**
>
> Deaths by deliberate or accidental overdosage have occurred with metaxalone, particularly in combination with antidepressants and have been reported with this class of drug in combination with alcohol.

Ex. 5, PTX 32, Sandoz's October 2009 metaxalone package insert.

However, none of these sections makes any reference to the p450 activity of any substance other than metaxalone or of possible p450-mediated interactions resulting from co-administration of metaxalone with another substance.[5] Sandoz's

[5] [redacted]

expert witnesses, Drs. Mayersohn and Palumbo, confirmed that Sandoz's package insert does not inform medical care workers of the p450 activity of any substance other than metaxalone ((Ex. 6, Sept. 14, 2010 trial tr., 132:4-9) ("Q. Now, anywhere on this label -- these sections of the label when they talk about the other substances, not Metaxalone, but these other substances, these CNS depressants and alcohol, etcetera, is there any discussion of any p450 activity at that point in the label? A. No, sir.") and 133:2-14 (Dr. Mayersohn); (Ex. 7, Sept. 13, 2010 trial tr., PM session, 13:12-15) (same) (Dr. Palumbo)).

The jury was also shown package inserts for drugs that do "inform" the reader, "for purposes of comprehension" (Ex. 4, *Post-Trial Jury Instructions and Jury Verdict Form*, p. 12), of possible p450 interactions with other drugs. The Crixivan® (generic name: indinavir) package insert (Ex. 8, DTX 137) states that: "Rifampin is a potent inducer of P450 3A4 that markedly diminishes plasma concentrations of indinavir. Therefore, CRIXIVAN and rifampin should not be coadministered." *Id.* at SAN00010992. The Crixivan package insert also states: "Calcium channel blockers are metabolized by CYP 3A4 which is inhibited by indinavir. Coadministration of CRIXIVAN with calcium channel blockers may result in increased plasma concentrations of the calcium channel blockers which could

[redacted].

increase or prolong their therapeutic and adverse effects." *Id; see also,* Ex. 9, DTX 138, Norvir package insert at SAN00010983, "Drug Interactions." Dr. Mayersohn explained to the jury that unlike the Sandoz package insert, the Crixivan and Norvir package inserts do "inform" others of possible p450 interactions with other drugs. Ex. 10, Sept. 15, 2010 trial tr., 18:4-28:20.

This evidence alone was sufficient for the jury to find that Sandoz's metaxalone package insert (unlike the package inserts for drugs such as Crixivan and Norvir) does not "inform" patients or medical care workers of the p450 activity of any substance other than metaxalone and, therefore, that Sandoz does not infringe claim 1.

Additional evidence also supports the jury's non-infringement verdict. Sandoz submitted evidence that the sections of its package insert relied upon by Plaintiffs concern an additive effect resulting from the co-administration of metaxalone with another central nervous system ("CNS") depressant, rather than a p450 mediated drug–drug interaction, including testimony of Dr. Sommerville, King's Vice President of Clinical Development. Ex. 6, Sept. 14, 2010 trial tr., 38:8-39:4 and Ex. 10, Sept. 15, 2010 trial tr., 34:5-40:14 (Dr. Mayersohn); Ex. 11, K. Sommerville, June 30, 2010 dep. tr., 117:19-118:5; 118:9-15; 118:19-25; 119:5-6 (read into evidence at trial, see Ex. 10, Sept. 15, 2010 trial tr., 117:12-15); Ex. 12, DTX 235; Ex. 13, DTX 237. This evidence also supports a finding that Sandoz's package insert

does not inform the patient or a medical care worker about the p450 activity of any substance other than metaxalone, and therefore also supports the jury's non-infringement verdict.

Plaintiffs in their JMOL brief argue that there is no requirement in the second part of the "informing" step that a patient or a medical care worker actually be informed that any substance other than metaxalone affects activity of a cytochrome p450 isozyme. Plaintiffs say that such a requirement is contrary to the "plain and ordinary meaning" of the claim and that Sandoz is attempting to add "extraneous limitations". According to Plaintiffs, it is sufficient if the other substance affects activity of a cytochrome p450 isozyme, but neither the patient nor a medical care worker need be informed of that fact. *See*, Plaintiff's JMOL brief, p.19 and n.6.

However, this clause of claim 1 was not construed by the Court, and the jury was instructed to give the clause its "common meaning." Ex. 1, Sept. 16, 2010 trial tr., 14:21-24 (jury charge). Plaintiffs' complaint boils down to a request for claim construction. But as the Federal Circuit explained in *Broadcom Corp. v. Qualcomm Inc.*, 543 F.3d 683, 696-697 (Fed. Cir. 2008), that request comes far too late:

> The term "selectively couples" was not construed by the district court because the parties agreed to let the ordinary meaning control.
> ...
> [W]e agree that "where the parties and the district court elect to provide the jury only with the claim language itself, and do not provide an interpretation of the language in the light of the specification and the prosecution history, it is too late at the JMOL

> stage to argue for or adopt a new and more detailed interpretation of the claim language and test the jury verdict by that new and more detailed interpretation." (citation omitted).

Moreover, when Sandoz filed a motion prior to trial for construction of this very clause of claim 1 [D.E. 220], Plaintiffs opposed, arguing that the clause was unambiguous and required no construction [D.E. 280, pp. 1-2]. The jury having returned a verdict of non-infringement, it is too late for Plaintiffs to revisit that issue now. Indeed, the passages in the '566 Patent cited by Plaintiffs in support of their belated request for claim construction (Plaintiffs' JMOL brief at p.19, n. 8) were never discussed at trial.

In the absence of an express claim construction, the jury was instructed to give this clause its common meaning, and Sandoz is entitled to an inference that the jury understood the clause as requiring that the package insert inform the patient or a medical care worker about the p450 activity of a substance other than metaxalone, and about possible p450 interactions between metaxalone and such substance. *Wagner*, 49 F.3d at 1012 (non-movant on JMOL entitled to "all logical inferences"). Indeed, that interpretation would be consistent with how this Court understood the clause when it denied Plaintiffs' motion for a preliminary injunction:

> Sandoz's label does not identify any other substance other than metaxalone, which appears to be required by claim 5. The relevant portion of claim 5 reads: "informing the patient . . . that administration of metaxalone and a substance that is a substrate, inhibitor, or inducer of CYP1A2 or CYP2C19 can affect plasma concentration, safety,

> efficacy or any combination thereof of metaxalone, the substance, or both." '566 Patent, 65:1-9. To infringe this claim, Sandoz's label would have to inform someone about administration of metaxalone and a substance. Sandoz's label does not speak to other substances besides metaxalone, or their relative interactions.[6]

D.E. 120, p. 8, *Memorandum Opinion* (emphasis in original).

Plaintiffs' argument that the medical doctors that provided expert testimony at trial "confirmed that the cytochrome p450 information on the current Skelaxin® drug label affects how the drug is prescribed to patients" misses the point. Plaintiffs' JMOL brief, p. 6; *see also id.* at p. 21. It is undisputed that the only p450 information on Sandoz's package insert concerns metaxalone. But that information only satisfies the first part of the "informing" step of claim 1, and has no bearing on whether Sandoz's metaxalone package insert also informs patients or medical care workers about the p450 activity of substances other than metaxalone. Equally irrelevant is a patient's or medical care worker's independent knowledge about the p450 activity of substances other than metaxalone (Plaintiffs' JMOL brief, pp. 6, 21), as Sandoz's label does not "inform" them of this information.

Because the jury's verdict that Sandoz does not infringe claim 1 is amply supported by evidence that the Sandoz package insert does not include information

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[6] The Court refers to claim 5, but the Court's analysis is equally applicable to claims 1 and 6, as all three independent claims require informing the patient or a medical care worker about p450 information of substances other than metaxalone.

concerning the p450 activity of any substance other than metaxalone, and does not include information about possible p450 interactions resulting from co-administration of metaxalone with another substance, the verdict should not be disturbed.

b) Independent Claims 5 and 6

Independent claims 5 and 6 also require "informing" the patient or medical care worker about the p450 activity of a substance other than metaxalone, and Plaintiffs' JMOL brief does not distinguish between those claims and claim 1. *See also* Ex. 6, Sept. 14, 2010 trial tr., 171:18-172:1 and 172:18-173:2 (Dr. Mayersohn). Therefore, for the same reasons that this Court should deny Plaintiffs' JMOL concerning infringement of claim 1, this Court should also deny Plaintiffs' JMOL motion concerning infringement of claims 5 and 6.

c) Dependent Claims

As noted above, the Court correctly charged the jury that if the independent claims are not infringed, then the dependent claims cannot be infringed. All of the other claims asserted against Sandoz, claims 2, 8 and 18-22, depend directly or indirectly on claims 1, 5 or 6. Therefore, because there was sufficient evidence for the jury to find that claims 1, 5 and 6 were not infringed, it follows that the jury verdict concerning the dependent claims should also not be disturbed.

2. There Was Sufficient Evidence to Support the Jury's Verdict That Sandoz Does Not Induce Infringement.

Since Plaintiffs failed to prove that Sandoz, or any other party, directly infringes any claim of the '566 Patent, Plaintiffs cannot succeed, as matter of law, on their claim that Sandoz induces infringement. *See,* Ex. 1, Sept. 16, 2010 trial tr., 17:20-18:8 (jury charge); *see also i4i L.P v. Microsoft Corp.*, 598 F.3d 831, 850 (Fed. Cir. 2010), *petition for cert. filed,* (U.S. Aug. 27, 2010) (No. 10-290) ("To succeed on a theory of contributory or induced infringement, i4i was required to show direct infringement of the '449 patent."); *Epcon Gas Systems, Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1033 (Fed. Cir. 2002) (same).

3. There Was Sufficient Evidence to Support the Jury's Verdict That the Asserted Claims Were Invalid for Anticipation and Obviousness.

In arguing that the asserted claims are not invalid, Plaintiffs refer to claim 1 as representative, and offer no separate argument for independent claims 5 and 6 or dependent claims 2, 8, and 18-22. Accordingly, Sandoz likewise addresses only claim 1 in responding to Plaintiffs' arguments that the claims are not invalid.

a) Anticipation

The jury found all asserted claims of the '566 patent invalid for anticipation. The Court charged the jury that Sandoz had the burden of proving by clear and convincing evidence that "each and every element in the claim [was] present in a

single item of prior art." Ex. 1, Sept. 16, 2010 trial tr., 20:8-10 (jury charge). The Court also instructed the jury that

> [i]n determining whether the single item of prior art anticipates a patent claim, you should take into consideration not only what is expressly disclosed in the particular item of prior art, but also what ... inherently resulted from the practice. ... To establish inherency, the evidence must make clear that the prior art necessarily resulted in the missing descriptive manner [sic, matter], and that it would be so recognized by a person of ordinary skill in the art at the time the patent application was filed. It is not required, however, that the person of ordinary skill would have recognized the inherent disclosure, thus the prior use of the patented invention that was unrecognized and unappreciated can still be invalidating anticipation.

Id., 20:17-21:6 (jury charge).

Plaintiffs argue they are entitled to JMOL because Sandoz did not introduce an expert opinion of anticipation at trial. Plaintiffs' JMOL brief, pp. 8-10. But the law imposes no such obligation, and a defendant asserting patent invalidity based on anticipation may rely on documents and testimony of the patentee's witnesses:

> In an effort to support the judgment in its favor, Blackboard relies on the district court's observation that Desire2Learn's expert witness on invalidity was ineffective at trial. Based on the court's observation, Blackboard contends that the jury was entitled to ignore the expert's testimony in its entirety. However, it is not necessary to rely on the testimony of Desire2Learn's witness to conclude that claims 36-38 are invalid. Instead, once the claims are properly construed, the conclusion of anticipation is dictated by the testimony of Blackboard's own witnesses and the documentary evidence that was presented to the jury.

Blackboard, Inc. v. Desire2Learn, Inc., 574 F.3d 1371, 1381-82 (Fed. Cir. 2009).

Plaintiffs do not dispute that the 2003 Skelaxin Label is prior art to the '566 Patent under 35 U.S.C. § 102(b), and at trial Sandoz presented substantial evidence that the 2003 Skelaxin Label anticipates all of the asserted claims. Ex. 14, PTX 2, at K000126-K000127.

The "DOSAGE AND ADMINISTRATION" section of the 2003 Skelaxin Label teaches the "providing" step of claim 1: "the recommended dose for adults and children over 12 years of age is two 400 mg tablets (800 mg) or one 800 mg tablet three to four times a day." *Id.*, at K000127. Indeed, Plaintiffs do not dispute that the "providing" step is taught by the 2003 Skelaxin Label. Plaintiffs' JMOL brief, p. 8.

As for the "informing" step of claim 1, that step only requires "informing" someone of the inherent results of taking metaxalone, results that have inherently occurred since metaxalone was first administered to patients in the early 1960s,[7] as Plaintiffs' own witnesses testified. Concerning the first part of the "informing" step, *i.e.*, that metaxalone affects the activity of a cytochrome p450 isozyme, Dr. Roberts, a named inventor on the '566 patent, gave the following testimony:

> Q: Now, could we go back to Claim 1, please, of the patent? This, again, talks about providing a patient with Metaxalone, right?

[7] The '566 patent, Ex. 2, PTX 1, at col. 1, lines 26-30, acknowledges that metaxalone was approved by the U.S. Food and Drug Administration (FDA) in 1962 as an adjunct to rest, physical therapy, and other measures for the relief of discomforts associated with acute, painful musculoskeletal conditions, such as muscles in spasm.

A. Yes. One component of a method of using Metaxalone, yes.

Q. And do you agree with me that every time you give Metaxalone it's interacting with the p450 system in the body?

A. Yes.

Q. Okay. And that's been true since 1962?

A. Yes.

Ex. 15, Sept. 13, 2010 trial tr., AM session, 47:12-22 (Dr. Roberts).

Q. Come back to that in one second. Doctor, just so we're clear, the patent we saw, the 566 Patent, you didn't invent cytochrome p450, right?

A. Oh, no.

Q. And you didn't invent metabolism, did you?

A. Well, right, of course not.

Ex. 16, Sept. 7, 2010 trial tr., 96:10-15 (Dr. Roberts).

Q. Now, before you answer that, you didn't invent – again, you didn't invent metabolism, you didn't invent induction, or inhibition, correct?

A. No. God did. That's how people were created.

Id., 120:4-7 (Dr. Roberts).

Plaintiffs' experts also testified that metaxalone's effect on p450 enzymes is inherent when metaxalone is administered to a patient.

Q. Okay. And you saw that Metaxalone was approved back in the early 1960's?

A. I believe some time in the 1960's. Yes.

Q. Okay. And when Metaxalone was being taken by patients back in the 1960's, was the same metabolism occurring back then that occurs now, in other words, that it went the same route you just described and metabolized the same way?

A. I would presume so. I don't think the Cytochrome P450s have evolved that much in the last 50 years.

Ex. 17, Sept. 8, 2010 trial tr., 130:2-10 (Dr. Guengerich).

Q. Okay. But the point is that these -- these -- these P450 enzymes, these proteins, they naturally occur in your body, and when you take a drug, they do what they naturally do.

A. Well, when you say naturally, this is not what we call a natural process. It's a bit unnatural, because these are unnatural compounds in general.

Q. But the body process is -- is happening by itself. In other words, it's all naturally occurring in your body.

A. Yes. All of the processes in your body are in that sense.

Id., 131:6-15 (Dr. Guengerich).

Q. Well, and when you -- when the patient takes Metaxalone, swallows the pill, it goes into their gut or wherever it goes, isn't it correct that the affect of those enzymes on Metaxalone is inherent to your body as a natural result in your body?

A. I'm not sure I understand the question.

Q. Well, let me pose the question this way. Do you agree with me that, to the extent the enzymes are actually involved in metabolism of Metaxalone, that they have actually always metabolized Metaxalone, even if it wasn't known before the studies were done to demonstrate that?

A. I think that's a fair statement, yes.

Ex. 18, Sept. 10, 2010 trial tr., AM session, 118:7-17 (Dr. Elia).

Concerning the second part of the "informing" step of claim 1, *i.e.*, "that administration of metaxalone with a substance that affects activity of a cytochrome p450 isozyme can affect plasma concentration, safety, efficacy or any combination thereof of metaxalone, the substance, or both," to the extent such interactions occur they too have inherently occurred whenever metaxalone was administered with another substance that affects activity of a p450 enzyme. Once again, Plaintiffs' witnesses confirmed this fact:

> Q. Okay. And would you also agree with me that when you give Metaxalone with another substance the way those two substances interact with the p450 system in the body has always been occurring?
>
> A. It has always been occurring. Well, it's a patient to patient specific situation. But, I mean, has ever occurred? Yes, sure.
>
> Q. Okay. And so, whatever that particular is who took it 30 years ago, whatever reaction he had he had naturally in his body when those two drugs interacted with the p450 system?
>
> A. You said occurred naturally. I mean, giving the drugs isn't a natural thing.
>
> Q. But, once they're in the body, the way they interact with the p450 system is a natural body process?
>
> A. I don't know about natural, but, yes, they're interacting with each other with the p450 system.
>
> Q. Okay.
>
> A. I didn't, as we said -- as I said the last time, I didn't create human beings or I didn't create livers. I didn't create p450 enzymes in people. I didn't -- you know. Not me.

Ex. 15, Sept. 13, 2010 trial tr., AM session, 47:23-48:17 (Dr. Roberts).

> Q. Okay. And likewise when a patient takes Metaxalone with another drug, to the extent that there is a p450 interaction occurring, that interaction is -- will always occur naturally in the body, right?
>
> A. Yes.
>
> Q. Okay. And, in fact, to the extent those p450 interactions were occurring between Metaxalone and other substances, they've been probably occurring since the day Metaxalone was first approved, right, and given with other drugs?
>
> A. That's probably true, yes.

Ex. 18, Sept. 10, 2010 trial tr., AM session, 118:18-119:2 (Dr. Elia).

The 2003 Skelaxin Label states, in the WARNINGS section, that: "SKELAXIN may enhance the effects of alcohol and other CNS depressants," and in the DRUG INTERACTIONS section, that: "SKELAXIN may enhance the effects of alcohol, barbiturates and other CNS depressants." Accordingly, the 2003 Skelaxin Label contemplates the co-administration of metaxalone with alcohol or other CNS depressants. The jury also heard evidence that alcohol and other CNS depressants affect the same p450 enzymes that metabolize metaxalone. Ex. 17, Sept. 8, 2010 trial tr., 61:20-65:21 (Dr. Guengerich); Ex. 18, Sept. 10, 2010 trial tr., AM session, 57:2-16 (Dr. Elia); Ex. 19, Sept. 10, 2010 trial tr., PM session, 23:5-17 (Dr. Gusmorino); Ex. 10, Sept. 15, 2010, trial tr., 75:19-21 (Dr. Mayersohn). From this evidence, and the testimony of Drs. Roberts and Elia cited above, the jury had ample evidentiary

support to find that the second part of the "informing" step of claim 1 is inherently disclosed by the 2003 Skelaxin Label.

Plaintiffs nevertheless argue that there can be no anticipation because the 2003 Skelaxin Label does not meet the "informing" requirement of the claim, *i.e.*, the 2003 Skelaxin Label does not expressly recite the inherent results of taking metaxalone with another substance. However, that argument ignores that inherent disclosures are, by definition, not expressly disclosed. Indeed, the Federal Circuit in *King Pharmaceuticals, Inc., et al. v. Eon Labs, Inc.*, 2009-1437, -1438, 2010 U.S. App. LEXIS 15947 (Fed. Cir. Aug. 2, 2010), *petition for reh'g and reh'g en banc denied* Oct. 14, 2010, has held that adding an "informing" requirement to a claim will not defeat anticipation where the "informing" step conveys inherent results of the method described in the anticipating reference:

> The specific question before us is whether an otherwise anticipated method claim becomes patentable because it includes a step of "informing" someone about the existence of an inherent property of that method. We hold it does not.

Id. at *28.

Likewise here, claim 1 calls for "informing" someone about the inherent result of taking metaxalone with another substance, and the jury correctly found that claim 1 is anticipated by the 2003 Skelaxin Label.

Plaintiffs also argue that Sandoz had a "very heavy burden" to prove anticipation because the anticipatory reference, the 2003 Skelaxin Label, was before the Patent Office during prosecution of the application that issued as the '566 Patent. Plaintiffs' JMOL brief, pp. 9-10. But there is no evidence that the Patent Office considered the evidence of inherency presented by Sandoz at trial, and the Federal Circuit has often affirmed holdings of anticipation by prior art that had been considered by the Patent Office. *See, e.g., King v. Eon*, 2010 U.S. App. LEXIS 15947, at *18-*19 and *23-*24; *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1381 (Fed. Cir. 2007). The Court charged the jury:

> When a party attacking the validity of a patent relies on prior art which was specifically considered by the examiner at the U.S. Patent and Trademark Office during the prosecution of the application leading to the issuance of the patent, that party bears the burden of overcoming the deference given to a qualified government agency official presumed to perform his or her job.

Ex. 1, Sept. 16, 2010 trial tr., 24:12-18. The only logical inference is that the jury concluded that Sandoz had met its burden of overcoming the deference accorded to qualified government officials. *Wagner*, 49 F.3d at 1012 (non-movant on JMOL entitled to "all logical inferences").

b) Obviousness

"Sandoz may establish that a patent claim is invalid by proving by clear and convincing evidence that the claimed invention would have been obvious to a person

having ordinary skill in the field of technology at the time the invention was made." Ex. 1, Sept. 16, 2010 trial tr., 21:13-17 (jury charge). The Court further instructed the jury that "[i]n determining whether a claimed invention is obvious, you must consider the level of ordinary skill in the field of pharmaceutical, pharmacological and medical science that someone would have had as of the filing date of the 566 Patent, October 14th, 2005, the scope and content of the prior art, and any differences between the prior art and the claimed invention." *Id.*, 21:18-24 (jury charge).

Experts for Plaintiffs and Sandoz gave testimony concerning the person of ordinary skill in the art of the '566 Patent. Sandoz's expert, Dr. Mayersohn, testified as follows:

> A. One of ordinary skilled in the art is a hypothetical person. It doesn't really exist as I understand it but who is very familiar with the literature in the areas that are being discussed. It's not an inventive person but nonetheless. I've offered three possibilities. One is a Bachelors in Pharmacy or Pharma D degree, at least a two-year residency or fellowship in the pharmaceutical industry or an academic setting providing similar training in pharmacokinetic principles and clinical pharmacology, or it's somebody with a Bachelors or Masters degree in Chemistry, Biology or Pharmaceutical Sciences or an M.D. degree and at least two years of experience in the pharmaceutical industry or an academic setting providing similar training in clinical pharmacology or at a higher level, a Ph.D. degree in Chemistry, Biology or Pharmaceutical Sciences or at least one year of industrial experience.

Ex. 6, Sept. 14, 2010 trial tr., 144:2-17.

Plaintiffs' expert, Dr. Guengerich, testified:

> A. I'll read it. "I have been asked to offer an opinion regarding the education and experience of a person of ordinary skill in the art to which the methods of the asserted claims of the 566 patent pertain. In my opinion, at the time the 566 patent was filed, a person of ordinary skill in the art would have at least the following credentials: 1) a B.S. or M.S. degree in chemistry, biology, pharmacy or pharmaceutical sciences or an M.D. degree; and 2) at least two years of experience related to drug pharmacology in a pharmaceutical industry or an academic or medical setting."

Ex. 17, Sept. 8, 2010 trial tr., 140:8-20.

The testimony of Sandoz's and Plaintiffs' experts concerning a person of ordinary skill in the art was similar. The person of ordinary skill was smart, having at least a college education and experience in pharmacology.

At trial, Sandoz argued that the '566 Patent claims would have been obvious to a person of ordinary skill in light of the 2003 Skelaxin Label (Ex. 14, PTX 2 at K000126-K000127), in combination with the 1999 FDA Guidance (Ex. 20, DTX 52) and the 1997 FDA Guidance (Ex. 21, DTX 51), which is a companion to the 1999 Guidance (the 1997 and 1999 FDA Guidances are collectively referred to as the "FDA Guidances").[8] Ex. 6, Sept. 14, 2010 trial tr., 145:7 – 183:21 (Dr. Mayersohn)

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[8] The 1999 Guidance (Ex. 20, DTX 52) explains that it is a companion to the 1997 Guidance (Ex. 21, DTX 51) and that the two should be read together:

> Previous guidance from FDA on the use of in vitro approaches to study drug metabolism and metabolic drug-drug interactions is available in a guidance document entitled *Drug Metabolism/Drug Interaction Studies in the Drug Development Process: Studies In Vitro (April 1997)*. The present guidance should be viewed as a companion to this earlier guidance.

(explaining that all asserted claims are invalid from the 2003 Skelaxin Label in view of the FDA Guidances).

As discussed above, Plaintiffs do not dispute that the DOSAGE AND ADMINISTRATION section of the 2003 Skelaxin Label teaches the "providing" step of claim 1: "the recommended dose for adults and children over 12 years of age is two 400 mg tablets (800 mg) or one 800 mg tablet three to four times a day." Ex. 14, PTX 2, at K000127.

The p450 information described in the "informing" step of claim 1 is based on *in vitro* studies reported in the specification of the patent. The FDA Guidances discuss the importance of testing both old and new drugs for p450 metabolism for the purpose of assessing potential p450 induced drug-drug interactions. Ex. 20, DTX 52, pp. 3, 5 and 11; Ex. 6, Sept. 14, 2010, trial tr., 121:10-125:7 and Ex. 10, Sept. 15, 2010 trial tr., 31:16-33:25 (Dr. Mayersohn). The 1997 FDA Guidance, in the section titled "Techniques and Approaches for Studies In Vitro of Drug Metabolism and Drug Interactions," explains how to carry out *in vitro* studies to determine which p450 enzymes metabolize a drug, which p450 enzymes are induced and inhibited by a drug (Ex. 21, DTX 51, p. 4 *et seq.*), and notes that such tests are "inexpensive and readily carried out." *Id.*, p.7. The 1999 FDA Guidance

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(Ex. 20, DTX52, at SAN00011016).

instructs that the results of such p450 testing -- whether positive or negative -- should be incorporated in the drug's package insert. (Ex. 20, DTX 52, pp. 13-16; Ex. 6, Sept. 14, 2010 trial tr., 160:24-164:19 and Ex. 10, Sept. 15, 2010 trial tr., 14:4-17:3 (Dr. Mayersohn)).[9,10]

Dr. Roberts testified that he conceived the invention of the '566 Patent no earlier than July 2005. Ex. 16, Sept. 7, 2010 trial tr., 85:3-13 (Dr. Roberts).[11] Thus, the *in vitro* testing that formed the basis for the '566 Patent was known to those of

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[9] The FDA Guidances were not cited by the Patent Office during prosecution of the '566 Patent.

[10] Dr. Roberts gave conflicting testimony as to whether he was aware of the FDA Guidances when the application for the '566 Patent was filed: "Q. Did you see this for [sic] FDA guidance [Ex. 21, DTX 51 (1997 FDA Guidance)] at any time before you deposition was taken, have you seen this? A. It was shown to me a few years after the patent. You know, I just said I saw it around the deposition time, but I think someone in the company showed this to me in the last year or so. I don't remember exactly." (Ex. 15, Sept. 13, 2010 trial tr., AM session, 30:21-31:1); but then later Dr. Roberts testified "Q. So, doctor, it's your testimony that you specifically told the Patent Office about these guidances that Mr. Pavane asked you about. A. Yes. When you say me, I mean, it was in the patent application. Q. It might have been done by your lawyers? A Right. I never spoke to the Patent Office myself directly, but in a sense I did, I mean, not by voice, but by documents I submitted we did. And the lawyers -- I don't have any experience with dealing directly with the Patent Office. The lawyers did that for us." (Ex. 15, Sept. 13, 2010 trial tr., AM session, 80:2-12).

[11] Although at trial and again in their JMOL brief, Plaintiffs refer to the invention of the '566 Patent as a "new method of treatment" (e.g., Plaintiffs' JMOL brief, p. 1), they have never explained what is "new" about the method of treatment claimed in the patent. "Providing" metaxalone to patients has been around since the 1960s when metaxalone was first approved by the FDA, and the "informing" step does not specify any treatment regimen at all, but rather only requires a conveyance of

ordinary skill in the art at least eight years before the inventors conceived the idea for the '566 Patent. The evidence also showed that the inventors of the '566 patent did nothing more than what the FDA Guidances recommended. Dr. Roberts testified that he contacted a third party contract research organization, In Vitro Technologies ("IVT"), to conduct the *in vitro* studies that became the basis for the '566 Patent. IVT prepared the protocols for the studies, and chose which p450 enzymes to test.

> Q. All right. But let me ask you this question, when you were doing this work in July of – well, when you thought of the idea in July of 2005 and you asked In Vitro to do this work was it known that there were certain P450 enzymes that were the predominant ones that were active in the body in breaking down drugs and acting on drugs?
>
> A. Yes.
>
> Q. Okay. And is in fact this a list of the predominant ones [looking at Ex. 22, PTX 136, Final Report for the metaxalone metabolism study conducted by In Vitro Technologies]?
>
> A. I don't know if this is a complete list, but I would venture to say these are -- at least some of these are, and maybe all of these are predominant ones.
>
> Q. Okay.
>
> A. In the P450 system.
>
> Q. And you didn't discover the predominant p450 enzymes that are involved in drug metabolism, did you?
>
> A. No. No. Of course we didn't.
>
> Q. Right. That was known, right?

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information.

A. Yes.

Q. Okay. So you asked In Vitro Technologies to take Metaxalone and test it against the known predominant P450 enzymes that were involved in -- normally involved in drug metabolism, is that fair?

A. Well, you say we asked. I wouldn't say we asked. We --

Q. You paid for it?

A. We engaged them, and we in a sense married our knowledge that we had of Metaxalone, analytical methods, solubility, characteristics, and the work that we did with the work that we contracted with them to do so that they could do that work effectively and we ended up with these results.

Ex. 16, Sept. 7, 2010 trial tr., 146:18-147:21 (Dr. Roberts).

Q. Okay. And they [In Vitro Technologies] say right below [looking at Ex. 23, DTX 315] that in the meantime, we are working on putting together the draft protocol for your study. Once we have put this together we will be e-mailing it to you for your review and changes that need to be made. Our goal is to have the protocol in place at the time we are done with the method development so that we can move – sorry -- right into starting your study, you see that?

A. Yes.

Q Okay. So, and again, just for the jury's sake, what's a protocol?

A. A protocol is the written procedure of how they're going to do, you know, these studies.

Q. Okay. So it would be the actual steps and the chemicals that they're going to use and whatever it is, the microsomes and --

A That's right.

Q. -- so on and so forth.

A. That's right.

Q. Right?

A. Yes.

Q. All right. So you get you get this e-mail from Tobi Limke on September 15th, 2005. And then let's look at the very last e-mail on the page which is right above that. And I think it's the same day. And this is you again writing back on September 15th, the same day back to Tobi, right?

A. Right, but four hours later.

Q. Right. And you say thanks, we will look at the protocol at Salamandra and our R&D group, however, this is your area of expertise not ours. So we will be depending upon your work. Right? You wrote that?

A. Right.

Ex. 16, Sept. 7, 2010 trial tr., 164:1-165:6; s*ee also* Ex. 24, B. Magrab, June 17, 2010 dep. tr., 277:16-19 and 24-25 ("Q. What was the reason that URL [a Pharma IP affiliate] did not run the substrate inducer and inhibitor studies that formed -- that are disclosed in the '566 patent, itself? A. Because we don't have the equipment or the expertise to run them."); 278:2-3; 278:6-8; 282:2-4; 282:8-11; 282:17 (read into evidence at trial, *see* Ex. 10, Sept. 15, 2010 trial tr., 116:3-11).

The Background section of the '566 Patent acknowledges that the p450 enzymes tested by IVT were the most common p450 enzymes involved in drug metabolism: "Cytochrome p450 isozymes identified as important in active agent metabolism are CYP1A2, CYP2A6, CYP2B6, CYP2C9, CYP2C19, CYP2D6, CYP2E1, and CYP3A4." (Ex. 2, PTX 1, '566 Patent, col. 2, lines 31-33). Plaintiffs'

expert Dr. Guengerich confirmed that at the time of invention it was known that the p450 enzymes IVT tested were involved in drug metabolism:

> Q. Now, Doctor, do you agree that there is a limited subset of the P450 enzymes that are responsible for the majority of metabolism in the liver?
>
> A. What do you mean, metabolism in the liver? Are you referring only to drugs?
>
> Q. I'm talking about drugs. Yes. This is all about drugs.
>
> A. All right. It's been estimated from these previous studies that I alluded to from Pfizer and Amgen Companies that five of the human Cytochrome P450s account for a sizable fraction of the -- of the oxidation of drugs.
>
> Q. Okay. And which ones are those, Doctor?
>
> A. Those are generally accepted to be P450 1A2, P450 2C9, 2C19, 2D6, and 3A4.
>
> Q. I'm sorry. You went a little fast. Would you mind doing that one more time? Just actually give me a second here. Let me just -- I'm sorry. Could you do that again?
>
> A. Sure. 1A2, 2C9, 2C19, 2D6, and 3A4.
>
> Q. Okay. How long has that been known?
>
> A. The only basis -- the basis for that has probably been on those papers that were published from the Pfizer and Amgen groups. So about five years.
>
> Q. 2004, 2005, in there?
>
> A. I can't -- I don't remember the exact dates, but some time about then.

Ex. 17, Sept. 8, 2010 trial tr., 152:25-153:23 (Dr. Guengerich).

Plaintiffs argue that one of ordinary skill in the art would have had no way of knowing that metaxalone would have interacted with p450 enzymes prior to the '566 Patent. Plaintiffs' JMOL brief, p. 13. But Plaintiffs' expert offered testimony to the contrary. Dr. Guengerich testified that as far back as 1966, it was known that metaxalone was metabolized by oxidation (Ex. 17, Sept. 8, 2010 trial tr., 133:22-135:9), and that it was also known that most metabolism by oxidation takes place in the liver and that roughly 85% of liver metabolism takes place via the cytochrome p450 system. *Id.*, 135:10-136:14. From this testimony the jury could have found that a person of ordinary skill would have recognized the likelihood that metaxalone was metabolized by the p450 enzyme system.

Dr. Guengerich also testified that at the time of the invention contract research laboratories were advertising the type of *in vitro* tests disclosed in the '566 Patent and that a person of ordinary skill could have found such contract research laboratories:

> Q. I want to make sure you answered my question. My question is directed to this somewhat fictional person of ordinary skill, and my question is could a person of ordinary skill, as you've defined that person, would that person know that there were contract research laboratories out there in June of 2005 that did these in vitro studies?
>
> A. They would be able to find contract laboratories that advertise these services.

Ex. 17, Sept. 8, 2010 trial tr., 146:17-24 (Dr. Guengerich).

Thus, the evidence showed that as early as 1997, the FDA was recommending that drugs be tested for p450 activity, that this recommendation extended to drugs already on the market, that the procedures for carrying out such *in vitro* testing were well known and available through third party contract laboratories, that the CYP enzymes tested by IVT on behalf of the inventors were those known to be most commonly involved in drug metabolism, and that the FDA recommended that the results of such *in vitro* testing be included on the drug's package insert. Moreover, the outcome of such *in vitro* tests were limited and well known – the tested drug either would or would not inhibit each p450 enzyme tested, would or would not induce each p450 enzyme, and was or was not metabolized by each p450 enzyme. Ex. 6, Sept. 14, 2010 trial tr., 150:15-153:9 (Dr. Mayersohn).

Despite this overwhelming evidence of obviousness, Plaintiffs argue that there was no evidence that one of ordinary skill in the art would have subjected metaxalone to the *in vitro* p450 testing recommended in the FDA Guidances. Plaintiffs' JMOL brief, pp. 11-15. In fact, there was substantial evidence on that issue. For example, Dr. Mayersohn testified:

> Q. All right, so if we go back and we look at the entirety of Claim 1 -- by the way, before I do that, you mentioned one thing. You said there would have been a motivation to conduct these tests on Metaxalone? You said that?
>
> A. Yes.

> Q. What is the basis for your saying there would have been a motivation to do that?
>
> A. Well, there are a few. For example, we know that --
>
> Q. Again, we're putting ourselves back in July of 2005, right --
>
> A Yeah.
>
> Q. -- prior to patent?
>
> A. We know that the so-called polypharmacy was extensively practiced meaning that people often took more than two or three drugs. We also know that the typical population associated with a need for musculoskeletal therapy like with Skelaxin is, like Dr. Palumbo said, tends to be an older population. Older populations tend to be more sensitive to drugs. Older populations often eliminate drugs, handle drugs differently than younger people. They have a greater incidence of adverse and drug-drug interactions. So it seems to me there was good motivation to have evaluated the drug-drug interactions with Metaxalone.

Ex. 6, Sept. 14, 2010 trial tr., 167:10-168:7.

As the Supreme Court recognized in its recent landmark decision on obviousness, "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007).

Plaintiffs' argument that there was no reason to have picked metaxalone for such testing, rather than the thousands of other drugs on the market, miscomprehends the law and finds no support in the Court's charge to the jury. In *KSR*, the invention

at issue was a pedal with a sensor. The Supreme Court explained that: "[t]he proper question to [ask is] ... whether a pedal designer of ordinary skill, facing the wide range of needs created by developments in the field of endeavor, would have seen a benefit to upgrading Asano [the prior art pedal] with a sensor." *KSR*, 550 U.S. at 424. Likewise here, from the evidence, including the testimony of Dr. Mayersohn cited above, the jury was justified in finding that a person of ordinary skill aware of the FDA Guidances would have seen the benefit of "upgrading" metaxalone by conducting the tests recommended in those FDA Guidances, and reporting the results -- positive or negative -- on the drug's package insert, as expressly recommended in the FDA Guidances. Ex. 20, DTX 52, pp.13-16; Ex. 6, Sept. 14, 2010 trial tr., 160:24-164:19 (Dr. Mayersohn). Indeed, a contrary finding would frustrate the rationale underlying the patent system:

> We build and create by bringing to the tangible and palpable reality around us new works based on instinct, simple logic, ordinary inferences, extraordinary ideas, and sometimes even genius. These advances, once part of our shared knowledge, define a new threshold from which innovation starts once more. And as progress beginning from higher levels of achievement is expected in the normal course, the results of ordinary innovation are not the subject of exclusive rights under the patent laws. Were it otherwise patents might stifle, rather than promote, the progress of useful arts.

KSR, 550 U.S. at 427.

Plaintiffs also argue that Sandoz's evidence of obviousness relies on improper hindsight. Plaintiffs' JMOL Brief, p. 14. The Court charged the jury that "In

determining whether the claimed invention was obvious, consider each claim separately. Do not use hindsight. In other words, consider only what was known at the time of the invention." Ex. 1, Sept. 16, 2010 trial tr., 23:6-9 (jury charge). The only reasonable inference is that the jury, mindful of the Court's charge, nevertheless found that the evidence rendered the claimed invention obvious. There was certainly sufficient evidence for the jury to find that it required no more than common sense by the person of ordinary skill – a college educated individual with pharmacological experience – to apply the teachings of the FDA Guidances to metaxalone, consistent with the Supreme Court's view:

> The Court of Appeals, finally, drew the wrong conclusion from the risk of courts and patent examiners falling prey to hindsight bias. A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning. See *Graham,* 383 U.S., at 36, 86 S.Ct. 684 (warning against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts to "'guard against slipping into the use of hindsight'" (quoting *Monroe Auto Equipment Co. v. Heckethorn Mfg. & Supply Co.,* 332 F.2d 406, 412 (6th Cir. 1964))). Rigid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it.

KSR, 550 U.S. at 421.

c) Dr. Palumbo Did Not Testify That The Invention Was Not Obvious

Plaintiffs argue that Sandoz's expert, Dr. Palumbo, admitted that the invention of the '566 Patent was not obvious. But Plaintiffs mischaracterize Dr. Palumbo's

testimony and take it out of context. Plaintiffs cite the following question and answer: "Q. It wasn't obvious to you, right? A. No." Plaintiffs' JMOL brief, p. 4. But the immediately preceding question and answer provide context:

> Q. And just so we're clear, Doctor, prior to reviewing the label that you've talked about, Sandoz label for Metaxalone, you were not aware that Metaxalone was a cytochrome p450 (indiscernible)?
>
> A. That's correct.
>
> Q. It wasn't obvious to you, right?
>
> A. No.

Ex. 7, Sept. 13, 2010 trial tr., PM session, 24:5-11 (Dr. Palumbo). In Plaintiffs' JMOL brief, Plaintiffs imply that Dr. Palumbo testified that the invention claimed in the '566 Patent was not obvious, but in context, it is clear that Dr. Palumbo was referring to the cytochrome p450 activity of metaxalone, not the claimed invention.

Furthermore, both Dr. Mayersohn's and Dr. Guengerich's descriptions of the person of ordinary skill in the art included experience in pharmacology. The other experts who testified at trial, Drs. Elia, Gusmorino, and Palumbo, lacked such pharmacological experience (Ex. 18, Sept. 10, 2010 trial tr., AM session, 38:23-44:21 (Dr. Elia); Ex. 19, Sept. 10, 2010 trial tr., PM session, 4:20-14:14 (Dr. Gusmorino); Ex. 15, Sept. 13, 2010 trial tr., AM session, 94:9-104:8 (Dr. Palumbo)), and the jury would have been right to find that they did not qualify as "persons of ordinary skill in the art," let alone experts in the art entitled to offer an opinion on obviousness.

Indeed, none of Drs. Elia, Guengerich or Palumbo offered direct testimony on the issue of obviousness. Rather, Plaintiffs used Drs. Elia and Gusmorino to explain physicians' prescribing practices, and Sandoz used Dr. Palumbo to rebut that testimony. Since Dr. Palumbo was not a person of ordinary skill in the art of the invention, the jury would have been correct to ignore his opinion concerning the obviousness of the invention had he offered one -- which he did not.

d) Secondary Considerations

The evidence at trial supported the jury's finding that secondary considerations did not overcome Sandoz's evidence that the '566 Patent claims were obvious.

Concerning secondary considerations the Court charged the jury that: "Plaintiffs have offered evidence of the following secondary considerations in this case. A, whether others copied the invention. And B, whether others sought or obtained rights to the patent from the patent holder." Ex. 1, Sept. 16, 2010 trial tr., 23:15-18.[12]

The only evidence of copying offered by Plaintiffs was that Sandoz copied the Skelaxin® drug label. However, copying the label does not constitute copying of the claimed invention, and the jury rejected that evidence when it found that Sandoz did not infringe the '566 Patent.

[12] The "commercial success" alleged by Plaintiffs in their JMOL brief (pp. 4, 15-16) was not before the jury. Sandoz presumes that Plaintiffs' JMOL brief is in

Regarding whether others sought rights in the '566 Patent, Plaintiffs' witness, James Green, admitted that the license between King and Mutual (Ex. 25, PTX 140) predated the '566 Patent, granted rights to the provisional application from which the '566 Patent issued (rather than the '566 Patent itself), and that royalty payments under the King-Mutual license were required whether or not the '566 Patent ever issued, and whether or not the '566 Patent was found to be invalid. Ex. 17, Sept. 8, 2010 trial tr., 18:15-23:14. Plaintiffs argue that there was a 5% "separate and additional royalty" solely for the patent rights licensed to King (Plaintiffs' JMOL brief, p.16, n.6), but the evidence Plaintiffs' cite for that proposition (Ex. O to Plaintiffs' Baton Declaration [D.E. 357-2], PTX 140, p.5) does not support it, as there is no mention there of the invention claimed in the '566 Patent. Based on the evidence, the jury rightly could have found that there was no nexus between the King-Mutual license agreement and the merits of the invention claimed in the '566 Patent.

Moreover, nothing in the Court's charge required the jury to find the '566 Patent just because it found that secondary considerations were present. The jury was fully justified in finding that secondary considerations, even if present, were insufficient to overcome the evidence of obviousness presented at trial. *See, Anderson's-Black Rock, Inc. v. Pavement Salvage Co., Inc.*, 396 U.S. 57, 61 (1969)

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error, and that Plaintiffs intended to refer to licensing, not commercial success.

("It is, however, fervently argued that the combination filled a long felt want and has enjoyed commercial success. But those matters 'without invention will not make patentability.'" (citation omitted)); *Leapfrog Enterprises, Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007) (affirming district court finding that "given the strength of the prima facie obviousness showing," the "substantial evidence of commercial success, praise, and long-felt need" could not overcome a final conclusion that the claim in question was obvious).

* * *

Because the evidence at trial was sufficient to support the jury's verdict of non-infringement and invalidity, Plaintiffs' motion for JMOL should be denied.

B. Motion for a New Trial

Alternatively, Plaintiffs argue for a new trial on validity and infringement. Like Plaintiffs' burden on their JMOL motion, Plaintiffs' burden on a motion for a new trial is high. *See Smith v. Holtz*, 210 F.3d 186, 200 (3d Cir. 2000) ("'The district court ought to grant a new trial on the basis that the verdict was against the weight of the evidence only where a miscarriage of justice would result if the verdict were to stand,'" quoting *Klein v. Hollings*, 992 F.2d 1285, 1290 (3d Cir. 1993)); *Williamson*, 926 F.2d at 1353, citing *EEOC v. Delaware Dep't of Health & Social Servs.*, 865 F.2d 1408, 1413 (3d Cir. 1989); *Church & Dwight Co. v. Abbott Labs.*, Civ. No. 05-2142, 2008 U.S. Dist. LEXIS 49581, *3 (D.N.J. June 24, 2008)

("'New trials because the verdict is against the weight of the evidence are proper only when the record shows that the jury's verdict resulted in a miscarriage of justice or where the verdict, on the record, cries out to be overturned or shocks our conscience,'" quoting *Vargo v. Coslet*, 126 Fed. Appx. 533, 534 (3d Cir. 2005)); *Matsushita Elec. Indus. Co.*, 2006 U.S. Dist. LEXIS 80145, *6 (same).

Here, the jury's verdict of non-infringement and invalidity was amply supported by the evidence adduced at trial. Allowing the jury's verdict to stand would neither constitute a miscarriage of justice nor shock the conscience. To the contrary, the jury's verdict was correct and Plaintiffs' motion for a new trial should be denied.

III. CONCLUSION

The question on Plaintiffs' motion is not whether there is evidence from which a fact finder could have found for Plaintiffs, but rather whether there was sufficient evidence to support the jury's verdict. Clearly there was, and Plaintiffs' motion for JMOL, or in the alterative, for a new trial, should be denied.

Dated: November 22, 2010

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CERTIFICATE OF SERVICE

This is to certify that a true and correct copy of the foregoing

SANDOZ'S OPPOSITION TO PLAINTIFFS' RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW, OR IN THE ALTERNATIVE, A NEW TRIAL, ON VALIDITY AND INFRINGEMENT (REDACTED VERSION)

is to be electronically filed. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system. A copy of same will also be served via electronic mail on all parties.

November 22, 2010
Date

/s/Eric I. Abraham
Eric I. Abraham